EXHIBIT H

-CONFIDENTIAL-

NEURONTIN (gabapentin)

SINGLE MOIETY PERIODIC REPORT

NDA #20-235

NDA #20-882

NDA #21-129

August 19, 2005 to August 18, 2006

Safety Surveillance and Reporting
Pfizer Inc
New York, New York

Prepared by
Inessa Neyman
Manager

October 12, 2006

PERIODIC REPORT

TABLE OF CONTENTS

PERIODIC REPORT

TABLE OF CONTENTS

PERIODIC REPORT

TABLE OF CONTENTS

U.S. Department of Health and Human Services
Food and Drug Administration

MEDWATCH

FORM FDA 3500A (10/05)

For use by user-facilities, importers, distributors and manufacturers for MANDATORY reporting

FDA Facsimile Approval: 05/09/2006 (ArisGlobal, LLC)

Mfr Report # 2006059400

UF/Importer Report #

FDA Use Only

A. PATIENT INFORMATION

1. Patient Identifier: Reda — In confidence
2. Age at Time of Event: Unk or Date of Birth:
3. Sex: [X] Female [ ] Male
4. Weight: ____ lbs or Unk ____ kgs

B. ADVERSE EVENT OR PRODUCT PROBLEM

1. [X] Adverse Event and/or [ ] Product Problem *(e.g., defects/malfunctions)*

2. Outcomes Attributed to Adverse Event *(Check all that apply)*
   - [X] Death: ____ *(mm/dd/yyyy)*
   - [ ] Life-threatening
   - [ ] Hospitalization - initial or prolonged
   - [ ] Required Intervention to Prevent Permanent Impairment/Damage (Devices)
   - [ ] Disability or Permanent Damage
   - [ ] Congenital Anomaly/Birth Defect
   - [ ] Other serious (Important Medical Events)

3. Date of Event *(mm/dd/yyyy)*: UNKNOWN

4. Date of This Report *(mm/dd/yyyy)*: 10/04/2006

5. Describe Event or Problem

This attorney reports, by means of a summons and complaint, that a female patient on an unknown dose of Neurontin (gabapentin) for an unspecified indication, successfully committed suicide. No further information is available at this time.

6. Relevant Tests/Laboratory Data, Including Dates

Initial (01May2006): Unknown

7. Other Relevant History, Including Preexisting Medical Conditions *(e.g., allergies, race, pregnancy, smoking and alcohol use, hepatic/renal dysfunction, etc.)*

Initial (01May2006): Unknown

Submission of a report does not constitute an admission that medical personnel, user facility, importer, distributor, manufacturer or product caused or contributed to the event.

3500A Facsimile

C. SUSPECT PRODUCT(S)

1. Name *(Give labeled strength & mfr/labeler)*
   #1 NEURONTIN (GABAPENTIN)
   #2

2. Dose, Frequency & Route Used
   #1 (UNKNOWN), UNKNOWN
   #2

3. Therapy Dates *(If unknown, give duration)* *from/to (or best estimate)*
   #1 UNKNOWN –
   #2

4. Diagnosis for Use *(Indication)*
   #1 Ill-defined disorder
   #2

5. Event Abated After Use Stopped or Dose Reduced?
   #1 [ ] Yes [ ] No [ ] Doesn't Apply — Unk
   #2 [ ] Yes [ ] No [ ] Doesn't Apply

6. Lot #
   #1
   #2

7. Exp. Date
   #1
   #2

8. Event Reappeared After Reintroduction?
   #1 [ ] Yes [ ] No [ ] Doesn't Apply — Unk
   #2 [ ] Yes [ ] No [ ] Doesn't Apply

9. NDC # or Unique ID

10. Concomitant Medical Products and Therapy Dates *(Exclude treatment of event)*

G. ALL MANUFACTURERS

1. Contact Office - Name/Address *(and Manufacturing Site for Devices)*

DSS
PFIZER INC
235 EAST 42ND STREET
NEW YORK, NY 10017
USA
(Initial Unit)

2. Phone Number: 212-573-3129

3. Report Source *(Check all that apply)*
   - [ ] Foreign
   - [ ] Study
   - [ ] Literature
   - [X] Consumer
   - [ ] Health Professional
   - [ ] User Facility
   - [ ] Company Representative
   - [ ] Distributor
   - [ ] Other:

4. Date Received by Manufacturer *(mm/dd/yyyy)*: 05/01/2006

5. (A)NDA # 20-235
   IND #
   STN #
   PMA/510(k) #
   Combination Product [ ] Yes
   Pre-1938 [ ] Yes
   OTC Product [ ] Yes

6. If IND, Give Protocol #

7. Type of Report *(Check all that apply)*
   - [ ] 5-day
   - [ ] 30-day
   - [ ] 7-day
   - [X] Periodic
   - [ ] 10-day
   - [X] Initial
   - [ ] 15-day
   - [ ] Follow-up #

9. Manufacturer Report Number: 2006059400

8. Adverse Event Term(s): 1) Suicide

E. INITIAL REPORTER

1. Name and Address

Phone # Redacted Patient In

Redacted Patient Information

2. Health Professional? [ ] Yes [X] No

3. Occupation: Not Applicable

4. Initial Reporter Also Sent Report to FDA? [ ] Yes [ ] No [X] Unk.

Periodic Report

NON 15-Day Report
Serious Labeled - Initial Report

Manufacturer's report # CTU #	Adverse Experience	Page no.
2005110262	Aphasia Asthenia Drug ineffective Dyspepsia Herpes virus infection Menopause	1
2005118265	Amnesia Loss of consciousness	3
2005120505	Cerebrovascular accident Depression Gastroenteritis viral Vomiting	5
2005120538	Convulsion Convulsion	7
2005121180	Drug ineffective Suicide attempt	9
2005126482	Drug ineffective Suicide attempt	11
2005127215	Deafness	13
2005128849	Drug ineffective Suicide attempt	15
2005128852	Drug ineffective for unapproved indication Suicidal ideation Suicide attempt	17
2005129734	Drug screen positive Incoherent Limb crushing injury	19
2005129768	Blood pressure increased Pain Panic attack	21
2005129868	Drug ineffective Suicide attempt	23
2005129869	Drug ineffective Overdose Suicide attempt	25
2005131124	Drug ineffective Suicide attempt	27
2005131125	Drug ineffective Suicide attempt	29

Periodic Report
NON 15-Day Report
Serious Labeled - Initial Report

Manufacturer's report # CTU #	Adverse Experience	Page no.
2005131126	Drug ineffective Suicide attempt	31
2005131127	Drug ineffective Suicide attempt	33
2005132286	Drug ineffective Suicide attempt	35
2005132299	Drug ineffective Suicide attempt	37
2005132308	Drug ineffective Suicide attempt	39
2005132311	Drug ineffective Suicide attempt	41
2005132312	Drug ineffective Suicide attempt	43
2005132315	Drug ineffective Suicide attempt	45
2005132317	Drug ineffective Suicide attempt	47
2005132357	Drug ineffective Suicide attempt	49
2005132642	Somnolence	51
2005133241	Drug ineffective Suicide attempt	53
2005133247	Drug ineffective Suicide attempt	55
2005133248	Drug ineffective Suicide attempt	57
2005133251	Drug ineffective for unapproved indication Intentional overdose Suicide attempt	59
2005133253	Drug ineffective Suicide attempt	61
2005133768	Pulmonary thrombosis	63
2005135055	Drug ineffective	64

Cont...

Periodic Report
NON 15-Day Report
Serious Labeled - Initial Report

Manufacturer's report # CTU #	Adverse Experience	Page no.
	Suicide attempt	
2005135076	Drug ineffective Suicide attempt	66
2005135347	Drug ineffective Suicide attempt	68
2005136088	Depression Drug ineffective Mood swings Suicide attempt	70
2005136315	Convulsion Drug ineffective Headache	72
2005136973	Deafness	74
2005137072	Convulsion Headache Malaise Pharmaceutical product complaint	76
2005137559	Encephalopathy	78
2005137636	Breast cancer Drug ineffective	80
2005139376	Body height decreased Cholelithiasis Drug ineffective Pain	82
2005140252	Drug ineffective Suicidal ideation Suicide attempt	85
2005140611	Drug ineffective Suicide attempt	87
2005140617	Drug ineffective for unapproved indication Suicide attempt	89
2005141192	Blood pressure diastolic decreased Drug ineffective	91
2005141576	Drug ineffective Haemorrhage Hypoaesthesia Limb injury	94
2005141837	Diarrhoea Lymphadenopathy Melaena	96

Cont...

Periodic Report
NON 15-Day Report
Serious Labeled - Initial Report

Manufacturer's report # CTU #	Adverse Experience	Page no.
	Weight decreased Weight increased	
2005143658	Dizziness	98
2005145440	Convulsion Nausea Tremor	100
2005145550	Goitre	102
2005145559	Drug ineffective Suicide attempt	103
2005145575	Deafness Hypoaesthesia Micturition disorder Migraine Tongue disorder Visual disturbance	105
2005146208	Convulsion	107
2005148982	Breast cancer Cardiac failure Fall Gait disturbance Injury Lung disorder Tremor	109
2005150112	Suicide attempt	111
2005151220	Drug ineffective Suicide attempt	112
2005151261	Drug ineffective Suicide attempt	114
2005151281	Drug ineffective Suicide attempt	116
2005151284	Drug ineffective Suicide attempt	118
2005151850	Deafness Faecal incontinence Sleep disorder	120
2005153649	Diarrhoea Dyspepsia Flatulence Malaise Menorrhagia Polymenorrhoea Pyrexia Rectal tenesmus Tremor	122

Cont...

Periodic Report

NON 15-Day Report
Serious Labeled - Initial Report

Manufacturer's report # CTU #	Adverse Experience	Page no.
2005154052	Amnesia Suicide attempt	124
2005155454	Drug ineffective Suicide attempt	126
2005156272	Anaemia Hallucination Personality disorder	128
2005156882	Drug ineffective Suicide attempt	131
2005157025	Drug ineffective Suicide attempt	133
2005157057	Drug ineffective Suicide attempt	135
2005157202	Transient ischaemic attack	137
2005158048	Back disorder Suicidal ideation Suicide attempt	139
20051591?9	Suicide attempt	141
2005159187	Drug ineffective Suicide attempt	142
2005159407	Adverse event Nausea Vomiting	144
2005159495	Angioneurotic oedema Bilirubin conjugated increased Blood alkaline phosphatase increased Blood bilirubin increased Blood sodium decreased	146
2005160431	Convulsion Vertigo	149
2005162349	Drug ineffective Suicide attempt	151
2005162350	Drug ineffective Suicide attempt	153
2005162353	Suicidal ideation	155
2005162364	Drug ineffective Suicide attempt	156

Cont...

Periodic Report

NON 15-Day Report
Serious Labeled - Initial Report

Manufacturer's report # CTU #	Adverse Experience	Page no.
2005162379	Convulsion	150
2005164812	Anorgasmia Convulsion	159
2005166859	Anxiety Completed suicide Drug ineffective Suicide attempt	161
2005169547	Amnesia Transient ischaemic attack	163
2005170543	Drug ineffective Suicide attempt	165
2005170555	Drug ineffective Suicide attempt	167
2005171846	Arthralgia Headache	169
2005172523	Suicide attempt	171
2006000297	Arthralgia Dry eye Glaucoma Keratitis Myalgia Pruritus Stress Tinea pedis Weight fluctuation	173
2006000317	Suicide attempt	175
2006000516	Liver function test abnormal	176
2006000518	Hypercholesterolaemia Liver function test abnormal	179
2006000858	Confusional state Convulsion Disorientation Dizziness Impaired driving ability Pain	182
2006003334	Drug ineffective Suicide attempt	184
2006003352	Drug ineffective Suicide attempt	186
2006003362	Drug ineffective for unapproved indication Suicide attempt	188

Cont...

Periodic Report

NON 15-Day Report
Serious Labeled - Initial Report

Manufacturer's report # CTU #	Adverse Experience	Page no.
2006005610	Convulsion	190
2006008881	Convulsion Feeling abnormal	192
2006009985	Drug ineffective Intentional overdose Suicide attempt	194
2006013225	Convulsion	196
2006014272	Dry mouth Oral discomfort Sleep disorder Tooth disorder Toothache	198
2006014936	Drug ineffective Suicide attempt	200
2006014963	Drug ineffective Suicide attempt	202
2006014970	Drug ineffective Suicide attempt	204
2006015761	Pain in extremity	206
2006016293	Suicide attempt	208
2006016300	Atrioventricular block Myocardial infarction	209
2006016632	Cataract	211
2006017213	Drug ineffective Suicide attempt	213
2006018710	Asthenia Confusional state Fear Increased appetite Mood swings Skin exfoliation Suicidal ideation Thinking abnormal Tremor Weight increased	215
2006018768	Accident Pruritus	218
2006018992	Suicide attempt	221
2006019416	Bronchitis Dizziness Drug ineffective	222

Cont...

Periodic Report
NON 15-Day Report
Serious Labeled - Initial Report

Manufacturer's report # CTU #	Adverse Experience	Page no.
	Somnolence	
2006019944	Depression Drug ineffective Migraine Pain Suicide attempt	224
2006022260	Drug ineffective Suicide attempt	228
2006022569	Drug ineffective Suicide attempt	230
2006027011	Aggression Agitation Amnesia Anorexia Anxiety Depression Feeling abnormal Insomnia Irritability Self-injurious ideation Suicidal ideation Suicidal ideation Suicide attempt	232
2006027781	Amnesia Coordination abnormal Depression Dizziness Emotional distress Fatigue Reading disorder Stomach discomfort Suicidal ideation Thinking abnormal Tremor Unevaluable event Vertigo Vision blurred	234
2006028638	Anxiety Drug ineffective Hepatic enzyme increased Insomnia Suicide attempt	237
2006029309	Drug ineffective Suicide attempt	239
2006029789	Dyspnoea Face oedema	241
2006030603	Drug ineffective Suicide attempt	243
2006030618	Drug ineffective Suicide attempt	245

Periodic Report
NON 15-Day Report
Serious Labeled - Initial Report

Manufacturer's report # CTU #	Adverse Experience	Page no.
2006030623	Drug ineffective Suicide attempt	247
2006030657	Completed suicide Drug ineffective Pain	249
2006031229	Cerebrovascular accident	251
2006031536	Depression Suicidal ideation	252
2006031543	Depression Suicide attempt	254
2006031549	Suicidal ideation	256
2006031552	Suicidal ideation	258
2006031554	Suicidal ideation	260
2006031566	Suicidal ideation	263
2006031567	Completed suicide	265
2006031578	Suicidal ideation	267
2006031580	Suicidal ideation	269
2006031600	Suicidal ideation	271
2006031606	Insomnia Suicidal ideation	273
2006031618	Suicidal ideation	275
2006031620	Affective disorder Anger Depression Suicidal ideation	277
2006031648	Suicidal ideation	280
2006031651	Suicidal ideation	282
2006031656	Suicidal ideation	284
2006031658	Suicidal ideation	286
2006031668	Suicidal ideation	288
2006031671	Suicidal ideation	290
2006031682	Suicidal ideation	292

Cont...

Periodic Report
NON 15-Day Report
Serious Labeled - Initial Report

Manufacturer's report # CTU #	Adverse Experience	Page no.
2006031720	Suicidal ideation	294
2006031732	Suicidal ideation	296
2006031733	Suicidal ideation	298
2006031736	Suicidal ideation	300
2006031744	Suicidal ideation	302
2006031747	Suicidal ideation	305
2006031749	Suicidal ideation	307
2006031755	Suicidal ideation	309
2006031758	Suicidal ideation	311
2006031759	Suicidal ideation Suicide attempt	313
2006031760	Suicidal ideation	315
2006031765	Suicidal ideation	317
2006031767	Bipolar disorder Depression Psychotic disorder Suicidal ideation	319
2006031769	Cerebrovascular accident	321
2006031796	Drug ineffective Suicidal ideation	325
2006031797	Suicidal ideation	328
2006031799	Suicidal ideation	330
2006031800	Completed suicide	332
2006031803	Suicidal ideation	334
2006031804	Suicidal ideation	336
2006031805	Suicidal ideation	338
2006031809	Suicidal ideation	340
2006031811	Suicidal ideation	342
2006031816	Suicidal ideation	344
2006031818	Suicidal ideation	346

Periodic Report
NON 15-Day Report
Serious Labeled - Initial Report

Manufacturer's report # CTU #	Adverse Experience	Page no.
2006031819	Suicidal ideation	340
2006031820	Suicidal ideation	350
2006031825	Suicidal ideation	353
2006031826	Suicidal ideation	355
2006031827	Anxiety Depressed mood Panic attack Suicidal ideation	357
2006031828	Suicidal ideation	359
2006031829	Accidental overdose Hallucination Paranoia Suicidal ideation	361
2006031837	Suicidal ideation	364
2006031914	Suicidal ideation	367
2006032689	Suicidal ideation	369
2006032696	Suicidal ideation	371
2006038975	Dizziness Drug ineffective Somnolence	373
2006039065	Depression Suicidal ideation	376
2006040903	Convulsion Drug effect decreased Drug ineffective	378
2006041213	Drug ineffective Suicide attempt	381
2006041218	Drug ineffective Suicide attempt	383
2006041219	Drug ineffective Suicide attempt	385
2006041609	Drug ineffective Suicide attempt	387
2006044832	Drug ineffective Suicide attempt	389

Periodic Report
NON 15-Day Report
Serious Labeled - Initial Report

Manufacturer's report # CTU #	Adverse Experience	Page no.
2006045034	Drug ineffective Suicide attempt	391
2006045038	Drug ineffective Suicide attempt	393
2006045042	Drug ineffective Suicide attempt	395
2006045045	Drug ineffective Suicide attempt	397
2006046265	Drug ineffective Suicide attempt	399
2006049037	Suicide attempt	401
2006049043	Suicide attempt	402
2006049192	Suicide attempt	404
2006049477	Suicide attempt	405
2006050868	Blister Dizziness Fatigue Hyperaemia Malaise Rash	406
2006051801	Drug ineffective Suicide attempt	411
2006052716	Drug ineffective Suicide attempt	413
2006055225	Cataract Drug ineffective Feeling drunk Hypoaesthesia Joint stiffness Oedema peripheral Sensory disturbance	415
2006058576	Drug ineffective Suicide attempt	418
2006058578	Drug ineffective Suicide attempt	420
2006058585	Drug ineffective Suicide attempt	422
2006058875	Suicidal ideation	424

Cont...

Periodic Report
NON 15-Day Report
Serious Labeled - Initial Report

Manufacturer's report # CTU #	Adverse Experience	Page no.
2006059398	Suicidal ideation	425
2006059399	Suicidal ideation	426
2006059400	Completed suicide	427
2006059401	Suicidal ideation	428
2006059402	Suicidal ideation	429
2006059403	Suicidal ideation	430
2006059404	Suicidal ideation	431
2006059405	Suicidal ideation	432
2006059406	Suicidal ideation	433
2006059407	Suicidal ideation	434
2006059408	Suicidal ideation	435
2006059409	Suicidal ideation	436
2006059410	Suicidal ideation	437
2006059411	Suicidal ideation	438
2006059412	Suicidal ideation	439
2006059413	Suicidal ideation	440
2006059414	Suicidal ideation	441
2006059416	Suicidal ideation	442
2006059417	Suicidal ideation	443
2006059419	Suicidal ideation	444
2006059420	Suicidal ideation	445
2006059421	Suicidal ideation	446
2006059422	Suicidal ideation	447
2006059424	Completed suicide	448
2006059429	Suicide attempt	449
2006059433	Completed suicide	450
2006059434	Suicidal ideation	451
2006059435	Suicidal ideation	452

Cont...

Periodic Report
NON 15-Day Report
Serious Labeled - Initial Report

Manufacturer's report # CTU #	Adverse Experience	Page no.
2006059436	Suicidal ideation	453
2006059438	Suicidal ideation	454
2006059440	Suicidal ideation	455
2006059441	Suicidal ideation	456
2006059442	Suicidal ideation	457
2006059443	Suicidal ideation	458
2006059444	Suicidal ideation	459
2006059445	Suicidal ideation	460
2006059448	Suicidal ideation	461
2006059449	Suicidal ideation	462
2006059450	Suicidal ideation	463
2006059451	Suicidal ideation	464
2006059452	Suicidal ideation	465
2006059453	Suicidal ideation	466
2006059456	Suicidal ideation	467
2006059457	Suicidal ideation	468
2006059458	Suicidal ideation	469
2006059459	Completed suicide	470
2006059460	Suicidal ideation	471
2006059461	Suicidal ideation	472
2006059462	Suicidal ideation	473
2006059466	Suicidal ideation	474
2006059468	Suicidal ideation	475
2006059469	Suicidal ideation	476
2006059471	Suicidal ideation	477
2006059472	Suicidal ideation	478
2006059473	Suicidal ideation	479
2006059474	Suicidal ideation	480

Cont...

Periodic Report
NON 15-Day Report
Serious Labeled - Initial Report

Manufacturer's report # CTU #	Adverse Experience	Page no.
2006059475	Completed suicide	481
2006059476	Suicidal ideation	482
2006059477	Suicidal ideation	483
2006059556	Suicidal ideation	484
2006059570	Suicidal ideation	485
2006059571	Suicidal ideation	486
2006061007	Pain Visual disturbance Weight increased	487
2006061015	Suicidal ideation	489
2006061379	Suicide attempt	490
2006061383	Suicide attempt	491
2006061384	Suicide attempt	492
2006061385	Suicide attempt	493
2006061386	Suicide attempt	494
2006061389	Suicide attempt	495
2006061390	Suicide attempt	496
2006061391	Suicide attempt	497
2006061393	Suicide attempt	498
2006061394	Suicide attempt	499
2006061395	Suicide attempt	500
2006061406	Suicide attempt	501
2006061407	Suicide attempt	502
2006061728	Myocardial infarction	503
2006062428	Drug ineffective Suicide attempt	505
2006062892	Asthma Dizziness Glaucoma Muscle spasms Oedema peripheral Somnolence Vision blurred	507

Cont...

Periodic Report

NON 15-Day Report
Serious Labeled - Initial Report

Manufacturer's report # CTU #	Adverse Experience	Page no.
2006063660	Drug ineffective Suicide attempt	509
2006063691	Drug ineffective Suicide attempt	511
2006063703	Drug ineffective Intentional overdose Suicide attempt	513
2006063719	Drug ineffective Suicide attempt	515
2006063734	Drug ineffective Intentional overdose Suicide attempt	517
2006065345	Suicide attempt	519
2006065757	Discomfort Drug effect decreased Feeling abnormal Neuralgia Vision blurred Weight increased	521
2006066314	Suicide attempt	524
2006066317	Suicide attempt	526
2006066318	Completed suicide	527
2006066320	Suicide attempt	528
2006066321	Suicide attempt	530
2006066322	Suicide attempt	532
2006066324	Completed suicide	534
2006066326	Suicide attempt	535
2006066329	Suicide attempt	537
2006066331	Suicide attempt	539
2006066738	Drug ineffective Suicide attempt	541
2006066743	Drug ineffective Suicide attempt	543
2006066744	Drug ineffective Suicide attempt	545

Cont...

Periodic Report
NON 15-Day Report
Serious Labeled - Initial Report

Manufacturer's report # CTU #	Adverse Experience	Page no.
2006066762	Drug ineffective Suicide attempt	547
2006066767	Drug ineffective Suicide attempt	549
2006066769	Drug ineffective Suicide attempt	551
2006067947	Constipation Diarrhoea Gastritis Pain Stomach discomfort Unevaluable event Weight increased	553
2006068610	Suicide attempt	557
2006068673	Drug ineffective Suicide attempt	558
2006068678	Drug ineffective Suicide attempt	560
2006069597	Suicide attempt	562
2006069794	Suicide attempt	563
2006069795	Suicide attempt	564
2006069797	Suicide attempt	565
2006069800	Suicide attempt	566
2006069801	Suicide attempt	567
2006069802	Suicide attempt	568
2006069803	Suicide attempt	569
2006069804	Suicide attempt	570
2006069806	Suicide attempt	571
2006069807	Suicide attempt	572
2006069808	Suicide attempt	573
2006069810	Suicide attempt	574
2006069812	Suicide attempt	575
2006069813	Suicide attempt	576

Periodic Report
NON 15-Day Report
Serious Labeled - Initial Report

Manufacturer's report # CTU #	Adverse Experience	Page no.
2006069814	Suicide attempt	577
2006069815	Suicide attempt	578
2006069816	Suicide attempt	579
2006069817	Suicide attempt	580
2006069818	Suicide attempt	581
2006069819	Suicide attempt	582
2006069821	Suicide attempt	583
2006069822	Suicide attempt	584
2006069823	Suicide attempt	585
2006069825	Suicide attempt	586
2006069826	Suicide attempt	587
2006069827	Suicide attempt	588
2006069828	Suicide attempt	589
2006069830	Suicide attempt	590
2006069831	Suicide attempt	591
2006069832	Suicide attempt	592
2006069834	Suicide attempt	593
2006069835	Suicide attempt	594
2006069836	Suicide attempt	595
2006069837	Completed suicide	596
2006069839	Suicide attempt	597
2006069841	Suicide attempt	598
2006069843	Suicide attempt	599
2006069844	Suicide attempt	600
2006069845	Suicide attempt	601
2006069847	Suicide attempt	602
2006069848	Suicide attempt	603
2006069849	Suicide attempt	604

Cont...

Periodic Report
NON 15-Day Report
Serious Labeled - Initial Report

Manufacturer's report # CTU #	Adverse Experience	Page no.
2006069851	Suicide attempt	605
2006069852	Suicide attempt	606
2006069854	Suicide attempt	607
2006069855	Suicide attempt	608
2006069856	Suicide attempt	609
2006069857	Suicide attempt	610
2006069858	Suicide attempt	611
2006069860	Suicide attempt	612
2006069861	Suicide attempt	613
2006069862	Suicide attempt	614
2006069865	Suicide attempt	615
2006069868	Suicide attempt	616
2006069870	Suicide attempt	617
2006069871	Suicide attempt	618
2006069873	Suicide attempt	619
2006069876	Suicide attempt	620
2006069877	Suicide attempt	621
2006069878	Completed suicide	622
2006069879	Suicide attempt	623
2006069880	Suicide attempt	624
2006069882	Suicide attempt	625
2006069883	Suicide attempt	626
2006069884	Suicide attempt	627
2006069885	Suicide attempt	628
2006069886	Suicide attempt	629
2006069887	Suicide attempt	630
2006072064	Fluid retention Hypotension Scar	631

Cont...

Periodic Report

NON 15-Day Report
Serious Labeled - Initial Report

Manufacturer's report # CTU #	Adverse Experience	Page no.
2006073850	Anxiety Feeling hot Headache Hypertension	633
2006076863	Completed suicide Drug ineffective	636
2006078558	Completed suicide Drug ineffective	638
2006080198	Completed suicide	640
2006080802	Dysphagia	641
2006080854	Back pain	643
2006081103	Pain Renal failure	645
2006081455	Drug ineffective Suicide attempt	648
2006081472	Aggression Completed suicide Drug ineffective Paranoia Psychotic disorder	650
2006081480	Drug ineffective Suicide attempt	652
2006081490	Drug ineffective Suicide attempt	654
2006085523	Suicidal ideation	656
2006086582	Completed suicide Drug ineffective	657
2006087838	Eczema Psoriasis	659
2006088609	Suicidal behaviour	662
2006088641	Depression Suicidal ideation Suicide attempt	663
2006088648	Drug ineffective Suicide attempt	665
2006088714	Completed suicide Drug ineffective	667

Cont...

Periodic Report
NON 15-Day Report
Serious Labeled - Initial Report

Periodic Report

Number of Adverse Experiences by Body System, Seriousness, Labeling and Geographic
Combined Initial/Follow-up Cases

Body System	Adverse Experience	Number of reports						
		Serious Unlabeled		Serious Labeled		Non Serious		Total
		Domestic	Foreign	Domestic	Foreign	Domestic	Foreign	
Blood and lymphatic system disorders								
	Anaemia			4	3	5		12
	Neutropenia		9					9
	Thrombocytopenia		1	2	3			6
	Blood disorder	2				3		5
	Lymphadenopathy			2		3		5
	Leukopenia				4			4
	Coagulopathy	1		1			1	3
	Eosinophilia		3					3
	Pancytopenia	2				1		3
	Anaemia macrocytic		2					2
	Agranulocytosis		1					1
	Aplastic anaemia	1						1
	Bone marrow disorder					1		1
	Bone marrow failure	1						1
	Haemolytic anaemia		1					1
	Hypercoagulation	1						1
	Iron deficiency anaemia	1						1
	Microcytic anaemia		1					1
	Platelet disorder						1	1
	Splenomegaly					1		1
	Thrombocytopenic purpura	1						1
	Thrombotic thrombocytopenic purpura		1					1
	White blood cell disorder				1			1
	Sub Totals	10	19	9	11	14	2	65
Cardiac disorders								
	Palpitations				1	17		18
	Myocardial infarction	2		13	1			16
	Cardiac arrest	11	2					13
	Cardiac failure congestive	4	1	6		1		12
	Cardiac disorder	5				6		11
	Coronary artery occlusion	11						11
	Angina pectoris			2		4		6
	Cardiac failure		1	4			1	6
	Cardiac valve disease	5				1		6
	Arrhythmia	2		1		1	1	5
	Tachycardia	1	1	1		1	1	5
	Atrial fibrillation			3	1			4
	Bradycardia		1		1	1		3
	Ventricular extrasystoles			2		1		3
	Cardiovascular disorder	1				1		2
	Cor pulmonale	2						2
	Acute coronary syndrome		1					1
	Acute myocardial infarction			1				1
	Angina unstable				1			1
	Aortic valve calcification	1						1
	Arteriosclerosis coronary artery					1		1
	Atrioventricular block			1				1
	Cardiac failure acute		1					1
	Cardiac failure chronic	1						1
	Cardiac flutter		1					1
	Cardio-respiratory arrest	1						1
	Cardiomegaly	1						1
	Cardiovascular deconditioning	1						1
	Coronary artery disease	1						1
	Cyanosis		1					1
	Dilatation ventricular	1						1
	Heart valve stenosis	1						1
	Hypertensive cardiomyopathy		1					1
	Mitral valve incompetence	1						1
	Myocardial ischaemia		1					1
	Pericardial effusion				1			1
	Pericardial fibrosis	1						1
	Postural orthostatic tachycardia syndrome					1		1
	Sinus tachycardia			1				1
	Supraventricular tachycardia	1						1
	Torsade de pointes		1					1
	Tricuspid valve disease	1						1
	Ventricular arrhythmia	1						1
	Ventricular fibrillation		1					1
	Sub Totals	57	14	35	6	36	3	151
Congenital, familial and genetic disorders								

Periodic Report

Number of Adverse Experiences by Body System, Seriousness, Labeling and Geographic
Combined Initial/Follow-up Cases

Body System	Adverse Experience	Number of reports						
		Serious Unlabeled		Serious Labeled		Non Serious		Total
		Domestic	Foreign	Domestic	Foreign	Domestic	Foreign	
								Cont...
	Facial dysmorphism	1				6		7
	Trisomy 21	2						2
	Ventricular septal defect	2						2
	Carbohydrate metabolism disorder					1		1
	Cleft lip		1					1
	Congenital anomaly	1						1
	Corneal dystrophy		1					1
	Factor V deficiency	1						1
	Homocystinaemia					1		1
	Hyperexplexia					1		1
	Macrognathia					1		1
	Neurofibromatosis		1					1
	Porphyria						1	1
	Spondylolisthesis	1						1
	Talipes		1					1
	Sub Totals	8	4			10	1	23
Ear and labyrinth disorders								
	Vertigo				3	12	3	18
	Tinnitus					15		15
	Deafness	1		8		2		11
	Hearing impaired		1	1		5		7
	Ear disorder	2				1		3
	Hypoacusis			1		2		3
	Meniere's disease	1				2		3
	Ear pain					2		2
	Cerumen impaction					1		1
	Deafness unilateral	1						1
	Ear discomfort		1					1
	Hyperacusis					1		1
	Inner ear disorder					1		1
	Motion sickness		1					1
	Vestibular disorder	1						1
	Sub Totals	6	3	10	3	44	3	69
Endocrine disorders								
	Hypothyroidism					7		7
	Thyroid disorder					4		4
	Goitre			1		1		2
	Hypothalamo pituitary disorders	1				1		2
	Acromegaly	1						1
	Adrenal disorder					1		1
	Adrenal insufficiency	1						1
	Basedow's disease					1		1
	Cushing's syndrome	1						1
	Diabetes insipidus	1						1
	Hyperprolactinaemia						1	1
	Inappropriate antidiuretic hormone secretion		1					1
	Thyroid cyst	1						1
	Sub Totals	6	1	1		15	1	24
Eye disorders								
	Vision blurred			8		78	2	88
	Visual disturbance			2	1	31		34
	Diplopia			2		16	1	19
	Cataract	3		10		4		17
	Eye disorder	2		2		13		17
	Visual acuity reduced	2		2	1	9	2	16
	Eye pain				1	14		15
	Dry eye				1	12	1	14
	Glaucoma	2		5		5		12
	Blindness	2		6	1	1		10
	Lacrimation increased					6		6
	Eye movement disorder					5		5
	Eye haemorrhage			4				4
	Eye irritation					4		4
	Macular degeneration	3				1		4
	Mydriasis	1				3		4
	Asthenopia					3		3
	Eyelid ptosis				2	1		3
	Photophobia					3		3
	Photopsia					3		3
								Cont...

Periodic Report

Number of Adverse Experiences by Body System, Seriousness, Labeling and Geographic
Combined Initial/Follow-up Cases

Body System	Adverse Experience	Number of reports						
		Serious Unlabeled		Serious Labeled		Non Serious		Total
		Domestic	Foreign	Domestic	Foreign	Domestic	Foreign	
	Blindness unilateral			2				2
	Cyanopsia					2		2
	Miosis				1		1	2
	Ocular hyperaemia					2		2
	Ophthalmoplegia	1				1		2
	Retinal disorder					1	1	2
	Abnormal sensation in eye					1		1
	Altered visual depth perception					1		1
	Astigmatism					1		1
	Blepharospasm					1		1
	Ciliary muscle spasm					1		1
	Conjunctivitis					1		1
	Dark circles under eyes					1		1
	Erythropsia					1		1
	Eye degenerative disorder					1		1
	Eye discharge					1		1
	Eye oedema					1		1
	Eye pruritus					1		1
	Eye rolling						1	1
	Eye swelling	1						1
	Eyelid pain					1		1
	Hypoaesthesia eye					1		1
	Keratitis					1		1
	Keratoconus					1		1
	Lens disorder					1		1
	Ocular icterus					1		1
	Ocular vascular disorder	1						1
	Optic nerve disorder					1		1
	Photokeratitis	1						1
	Pupil fixed		1					1
	Refraction disorder					1		1
	Retinal artery occlusion	1						1
	Retinal haemorrhage		1					1
	Retinal oedema		1					1
	Retinal vein thrombosis				1			1
	Strabismus	1						1
	Ulcerative keratitis					1		1
	Uveitis		1					1
	Visual brightness					1		1
	Sub Totals	21	4	43	9	240	9	326
Gastrointestinal disorders								
	Nausea	1		2	4	85	6	98
	Diarrhoea			5	3	52	1	61
	Dry mouth			1		51	3	55
	Vomiting	1		10	3	37	4	55
	Constipation			1		36	2	39
	Abdominal pain upper			1		26	1	28
	Dysphagia	3		5	2	16	1	27
	Stomach discomfort					27		27
	Gastrooesophageal reflux disease	1				20		21
	Abdominal pain			3		13	1	17
	Dyspepsia					16		16
	Abdominal distension					13	1	14
	Flatulence					10		10
	Tooth disorder			3		6		9
	Tooth loss	1	2			5		8
	Abdominal discomfort					7		7
	Faecal incontinence			1		6		7
	Gastric disorder					7		7
	Gastrointestinal disorder	3		1		3		7
	Hiatus hernia	1				6		7
	Irritable bowel syndrome	1		2		3	1	7
	Haemorrhoids			1		5		6
	Retching	1				5		6
	Swollen tongue	1	1			2	1	5
	Coeliac disease	2				2		4
	Pancreatic disorder	3	1					4
	Pancreatitis	1		3				4
	Bowel sounds abnormal	1				2		3
	Gastric ulcer			1		2		3
	Gastrointestinal haemorrhage	1	1			1		3
	Gingival disorder					3		3
	Hypoaesthesia oral		1			1	1	3
	Oesophageal spasm	1		1		1		3
	Stomatitis					3		3
	Tooth discolouration					3		3

Cont...

Periodic Report

Number of Adverse Experiences by Body System, Seriousness, Labeling and Geographic
Combined Initial/Follow-up Cases

Body System	Adverse Experience	Number of reports						
		Serious Unlabeled		Serious Labeled		Non Serious		Total
		Domestic	Foreign	Domestic	Foreign	Domestic	Foreign	
	Toothache					3		3
	Abdominal rigidity	1				1		2
	Dental plaque					2		2
	Eructation					2		2
	Gastritis					2		2
	Gastrointestinal motility disorder	1				1		2
	Glossodynia					1	1	2
	Haematemesis			2				2
	Impaired gastric emptying	1				1		2
	Intestinal functional disorder					2		2
	Melaena			1		1		2
	Oral discomfort					2		2
	Paraesthesia oral					1	1	2
	Rectal haemorrhage			1		1		2
	Regurgitation of food					2		2
	Tongue disorder					2		2
	Tooth malformation		2					2
	Abdominal adhesions	1						1
	Abdominal symptom					1		1
	Abdominal tenderness					1		1
	Abnormal faeces					1		1
	Acute abdomen	1						1
	Anal discomfort					1		1
	Anal sphincter atony					1		1
	Aphagia	1						1
	Aptyalism					1		1
	Ascites	1						1
	Barrett's oesophagus	1						1
	Bowel movement irregularity					1		1
	Crohn's disease					1		1
	Diverticulum					1		1
	Epigastric discomfort					1		1
	Frequent bowel movements					1		1
	Gastric haemorrhage	1						1
	Gastrointestinal hypomotility		1					1
	Gastrointestinal mucosal disorder					1		1
	Gastrointestinal pain					1		1
	Gastrointestinal ulcer					1		1
	Gingival hyperplasia					1		1
	Gingival pain					1		1
	Gingival recession					1		1
	Gingival swelling					1		1
	Haemorrhoidal haemorrhage						1	1
	Hyperchlorhydria					1		1
	Intestinal infarction	1						1
	Intestinal prolapse	1						1
	Intestinal strangulation	1						1
	Lip pain						1	1
	Loose tooth		1					1
	Mouth ulceration					1		1
	Odynophagia		1					1
	Oesophageal achalasia	1						1
	Oesophageal disorder					1		1
	Oesophageal pain					1		1
	Oesophageal ulcer	1						1
	Oral mucosal blistering					1		1
	Pancreatitis acute			1				1
	Parotid gland enlargement					1		1
	Periodontitis					1		1
	Peritoneal disorder	1						1
	Proctalgia					1		1
	Rectal discharge					1		1
	Rectal prolapse	1						1
	Rectal tenesmus					1		1
	Reflux gastritis					1		1
	Retroperitoneal haematoma	1						1
	Salivary hypersecretion					1		1
	Sensitivity of teeth					1		1
	Steatorrhoea					1		1
	Stress ulcer					1		1
	Tongue exfoliation					1		1
	Tongue haemorrhage					1		1
	Tongue oedema						1	1
	Tongue ulceration					1		1
	Tooth erosion					1		1
	Umbilical hernia					1		1
	Volvulus		1					1

Cont...

Periodic Report

Number of Adverse Experiences by Body System, Seriousness, Labeling and Geographic
Combined Initial/Follow-up Cases

Body System	Adverse Experience	Number of reports						
		Serious Unlabeled		Serious Labeled		Non Serious		Total
		Domestic	Foreign	Domestic	Foreign	Domestic	Foreign	
	Sub Totals	40	12	46	12	537	28	675
General disorders and administration site conditions								
	Drug ineffective			24	2	775	16	817
	Pain	10	6	7	1	293	7	324
	Feeling abnormal	2				134	4	140
	Fatigue	1			1	114	11	127
	Uncvaluablc cvcnt	12	1			64	1	78
	Oedema peripheral		1	4	5	61	3	74
	Drug effect decreased					72		72
	Malaise	2	2	4	4	55	2	69
	Asthenia	3	1	7	2	50	2	65
	Drug interaction	8	9		3	42	2	64
	Adverse event	13	1			48		62
	Difficulty in walking	12	3		1	44		60
	Gait disturbance	1			2	32	4	39
	Swelling	2		2		33		37
	Drug withdrawal syndrome	5	6	1	1	19	1	33
	Abasia	24	2			4		30
	Feeling drunk	1				25		26
	Irritability					23	3	26
	Chest pain			7		11	1	19
	Drug intolerance					17	2	19
	Oedema	1	1	3	3	11		19
	Chest discomfort	1				16	1	18
	Pyrexia	1	1	5	1	10		18
	Ill-defined disorder	2				15		17
	Therapeutic response decreased					17		17
	Death	8	5					13
	Discomfort					12	1	13
	Feeling cold		1			12		13
	Adverse drug reaction	2				8		10
	Disease progression	2	1			7		10
	Drug ineffective for unapproved indication					10		10
	Chills	1			1	7		9
	Feeling hot		1			8		9
	General physical health deterioration	4				5		9
	Peripheral coldness	1	1			7		9
	Breakthrough pain					7		7
	Feeling jittery					7		7
	Influenza like illness					7		7
	Thirst					7		7
	Condition aggravated		2			4		6
	Facial pain	1				5		6
	Inflammation	1				4	1	6
	Drug resistance					5		5
	Ulcer	2		1		1	1	5
	Hangover					4		4
	Local swelling	1				3		4
	Sluggishness					4		4
	Energy increased	1				1	1	3
	Hernia			1		2		3
	Hunger					3		3
	Inadequate analgesia					3		3
	Loss of control of legs					3		3
	Chronic fatigue syndrome	1				1		2
	Deformity	2						2
	Drug tolerance	1				1		2
	Face oedema			1	1			2
	Generalised oedema			1		1		2
	Impaired healing					2		2
	Multi-organ failure	2						2
	Tenderness					2		2
	Therapeutic response delayed					2		2
	Adhesion					1		1
	Atrophy	1						1
	Brain death	1						1
	Calcinosis					1		1
	Cyst					1		1
	Developmental delay		1					1
	Drug effect increased					1		1
	Exercise tolerance decreased					1		1
	Feeling hot and cold					1		1
	Feeling of relaxation					1		1
	General symptom					1		1

Periodic Report

Number of Adverse Experiences by Body System, Seriousness, Labeling and Geographic
Combined Initial/Follow-up Cases

Body System	Adverse Experience	Number of reports						
		Serious Unlabeled		Serious Labeled		Non Serious		Total
		Domestic	Foreign	Domestic	Foreign	Domestic	Foreign	
								Cont . . .
	Hyperthermia		1					1
	Hypothermia						1	1
	Inflammatory pain					1		1
	Mucous membrane disorder					1		1
	No adverse drug effect					1		1
	No adverse effect					1		1
	No therapeutic response	1						1
	Nodule					1		1
	Non-cardiac chest pain					1		1
	Nonspecific reaction					1		1
	Paradoxical drug reaction					1		1
	Performance status decreased					1		1
	Pharmaceutical product complaint					1		1
	Pitting oedema					1		1
	Premature ageing					1		1
	Sensation of pressure					1		1
	Symptom masked					1		1
	Tachyphylaxis					1		1
	Temperature intolerance					1		1
	Therapeutic response increased					1		1
	Therapeutic response unexpected					1		1
	Therapeutic response unexpected with drug substitution					1		1
	Therapy non-responder						1	1
	Ulcer haemorrhage	1						1
	Sub Totals	135	47	68	28	2167	66	2511
Hepatobiliary disorders								
	Liver disorder	2	2			4		8
	Cholelithiasis		1	3				4
	Cytolytic hepatitis		4					4
	Hepatitis		2	1	1			4
	Cholestasis		3					3
	Hepatocellular damage	2	1					3
	Jaundice	1			2			3
	Hepatic cirrhosis	1	1					2
	Hepatic failure	2						2
	Hepatic steatosis	1	1					2
	Hepatitis toxic		2					2
	Hepatotoxicity	2						2
	Bile duct stenosis	1						1
	Gallbladder disorder	1						1
	Hepatic congestion	1						1
	Hepatic function abnormal				1			1
	Hepatic necrosis	1						1
	Hepatitis alcoholic	1						1
	Hepatitis cholestatic		1					1
	Hepatomegaly					1		1
	Jaundice cholestatic		1					1
	Jaundice hepatocellular				1			1
	Sub Totals	16	19	4	5	5		49
Immune system disorders								
	Hypersensitivity		2	8	1	42		53
	Drug hypersensitivity			1		7		8
	Immune system disorder	3						3
	Multiple allergies					3		3
	Anaphylactic reaction	2						2
	Immunodeficiency	1				1		2
	Anaphylactoid reaction	1						1
	Autoimmune disorder		1					1
	Graft versus host disease	1						1
	Reaction to colouring					1		1
	Sarcoidosis	1						1
	Sub Totals	9	3	9	1	54		76
Infections and infestations								
	Herpes zoster					18		18
	Pneumonia	1	1	13		3		18
	Bronchitis			1		8		9
	Infection	2		3	1	2		8
								Cont...

Periodic Report

Number of Adverse Experiences by Body System, Seriousness, Labeling and Geographic
Combined Initial/Follow-up Cases

Body System	Adverse Experience	Number of reports						
		Serious Unlabeled		Serious Labeled		Non Serious		Total
		Domestic	Foreign	Domestic	Foreign	Domestic	Foreign	
	Sinusitis					8		8
	Urinary tract infection					8		8
	Cystitis					7		7
	Gastroenteritis viral					7		7
	Nasopharyngitis					7		7
	Staphylococcal infection	7						7
	Diverticulitis	3				2	1	6
	Influenza					6		6
	Cellulitis			3		1		4
	Dental caries					3		3
	Hepatitis C	1	1	1				3
	Kidney infection					3		3
	Lung infection			1		2		3
	Oral candidiasis		1			2		3
	Osteomyclitis	2				1		3
	Viral infection					3		3
	Abscess	1		1				2
	Bacteraemia	2						2
	Clostridial infection	1				1		2
	Epstein-Barr virus infection					2		2
	Eye infection					2		2
	Fungal infection					2		2
	Gastroenteritis		1			1		2
	Herpes virus infection					2		2
	Lyme disease	2						2
	Post polio syndrome	1				1		2
	Sepsis	1		1				2
	Tinea pedis					2		2
	Upper respiratory tract infection					2		2
	Acquired immunodeficiency syndrome	1						1
	Appendicitis	1						1
	Arthritis infective	1						1
	Babesiosis					1		1
	Bacterial infection	1						1
	Bronchitis acute			1				1
	Bronchitis chronic					1		1
	Bronchopneumonia			1				1
	Candidiasis					1		1
	Dacryocystitis infective	1						1
	Ear infection					1		1
	Enterococcal infection	1						1
	Gingival infection					1		1
	Hepatitis A	1						1
	Hepatitis B	1						1
	Hepatosplenic candidiasis		1					1
	Herpes simplex					1		1
	Infectious mononucleosis					1		1
	Localised infection					1		1
	Lower respiratory tract infection					1		1
	Lung infection pseudomonal	1						1
	Onychomycosis					1		1
	Orchitis	1						1
	Pharyngitis					1		1
	Pneumonia haemophilus	1						1
	Pneumonia mycoplasmal			1				1
	Pseudomonas infection	1						1
	Rhinitis					1		1
	Sinusitis bacterial					1		1
	Tooth abscess					1		1
	Viral rash						1	1
	Viral upper respiratory tract infection					1		1
	Vulvovaginal mycotic infection					1		1
	Wound infection					1		1
	Sub Totals	36	5	27	1	123	2	194
Injury, poisoning and procedural complications								
	Fall	23	8	4		38	2	75
	Overdose	32	2	3	1	4		42
	Intentional overdose	22		8	1	4		35
	Nerve injury	12	1			12		25
	Drug toxicity	8	5			4		17
	Road traffic accident	11		2		4		17
	Gun shot wound	16						16

Cont...

Periodic Report

Number of Adverse Experiences by Body System, Seriousness, Labeling and Geographic
Combined Initial/Follow-up Cases

Body System	Adverse Experience	Number of reports						
		Serious Unlabeled		Serious Labeled		Non Serious		Total
		Domestic	Foreign	Domestic	Foreign	Domestic	Foreign	
	Injury	7	2			6		15
	Drug administration error	1	1	2		10		14
	Drug exposure during pregnancy	4	4			6		14
	Intentional drug misuse	1		1		11	1	14
	Contusion				3	9		12
	Joint dislocation	5				2		7
	Medication error	4	1			2		7
	Multiple drug overdose intentional	5		1				6
	Accident	2		1		2		5
	Alcohol poisoning	5						5
	Foot fracture	1		3		1		5
	Head injury	2			1	2		5
	Thermal burn	3				1	1	5
	Back injury			1		3		4
	Drug dispensing error	1	1			2		4
	Joint injury	1				3		4
	Limb injury	1				3		4
	Lower limb fracture	2		2				4
	Traumatic brain injury	4						4
	Accidental exposure	1				2		3
	Accidental overdose	1	1			1		3
	Ankle fracture	2		1				3
	Concussion	3						3
	Facial bones fracture	3						3
	Fracture			2		1		3
	Intervertebral disc injury	2				1		3
	Poor quality drug administered					3		3
	Subdural haematoma	1		2				3
	Tooth injury					3		3
	Upper limb fracture	2		1				3
	Cervical vertebral fracture	2						2
	Closed head injury	2						2
	Device failure	1				1		2
	Difficult to wean from ventilator	2						2
	Drug prescribing error					2		2
	Face injury					2		2
	Gastrointestinal stoma complication	1	1					2
	Haemothorax	2						2
	Incorrect dose administered	1				1		2
	Joint sprain					2		2
	Ligament injury	1				1		2
	Ligament rupture	2						2
	Limb crushing injury	1		1				2
	Lung injury	1				1		2
	Multiple drug overdose	1	1					2
	Muscle strain					2		2
	Post procedural complication	2						2
	Procedural pain		1			1		2
	Rib fracture	1				1		2
	Skull fracture	2						2
	Spinal cord injury	2						2
	Tendon injury	2						2
	Therapeutic agent toxicity		1			1		2
	Accident at home	1						1
	Anticonvulsant toxicity	1						1
	Arthropod bite					1		1
	Brachial plexus injury					1		1
	Brain herniation	1						1
	Burns second degree	1						1
	Burns third degree	1						1
	Carbon monoxide poisoning	1						1
	Caustic injury	1						1
	Clavicle fracture			1				1
	Compression fracture	1						1
	Coronary artery restenosis			1				1
	Drug dose omission					1		1
	Drug exposure via breast milk					1		1
	Dural tear	1						1
	Ear injury	1						1
	Eye injury	1						1
	Femur fracture		1					1
	Fractured coccyx					1		1
	Fractured sacrum	1						1
	Gastrointestinal injury	1						1
	Graft complication					1		1

Cont...

Periodic Report

Number of Adverse Experiences by Body System, Seriousness, Labeling and Geographic
Combined Initial/Follow-up Cases

Body System	Adverse Experience	Number of reports						
		Serious Unlabeled		Serious Labeled		Non Serious		Total
		Domestic	Foreign	Domestic	Foreign	Domestic	Foreign	
	Hand fracture	1						1
	Hip fracture	1						1
	Incisional hernia	1						1
	Incorrect drug administration duration					1		1
	Incorrect route of drug administration					1		1
	Internal injury					1		1
	Intracranial injury	1						1
	Intraocular lens dislocation	1						1
	Laceration	1						1
	Ligament sprain					1		1
	Lumbar vertebral fracture	1						1
	Meniscus lesion	1						1
	Mouth injury					1		1
	Multiple fractures			1				1
	Muscle injury					1		1
	Narcotic intoxication		1					1
	Neck injury	1						1
	Nerve root injury lumbar	1						1
	Open wound	1						1
	Pelvic fracture	1						1
	Peroneal nerve injury					1		1
	Poisoning	1						1
	Polytraumatism					1		1
	Post laminectomy syndrome					1		1
	Procedural complication					1		1
	Procedural site reaction					1		1
	Pubic rami fracture	1						1
	Scratch						1	1
	Seroma	1						1
	Skeletal injury					1		1
	Skin injury				1			1
	Skin laceration					1		1
	Skull fractured base	1						1
	Spinal fracture	1						1
	Suture rupture	1						1
	Thoracic vertebral fracture	1						1
	Tooth fracture					1		1
	Treatment noncompliance					1		1
	Vertebral injury	1						1
	Vth nerve injury					1		1
	Wound dehiscence	1						1
	Sub Totals	248	32	38	7	177	5	507
Investigations								
	Weight increased			21	4	123	2	150
	Weight decreased			11		44	3	58
	Body height decreased					42		42
	Blood cholesterol increased					37	1	38
	Blood pressure increased	1		4		18		23
	Heart rate increased	1		3		17		21
	Blood glucose increased		1	2		13		16
	Blood pressure decreased			3	2	5		10
	Hepatic enzyme increased				3	6	1	10
	Blood sodium decreased	2		1		4	1	8
	Drug screen positive	1				6		7
	Heart rate decreased	2		2	1	1	1	7
	Alanine aminotransferase increased		2		2	2		6
	Blood alkaline phosphatase increased			1	2	3		6
	Blood creatinine increased	1	2			3		6
	Blood triglycerides increased					6		6
	Heart rate irregular		1	1		4		6
	Medication residue					6		6
	Anticonvulsant drug level increased		1			4		5
	Blood cholesterol abnormal					5		5
	Blood creatine phosphokinase increased	1	1			3		5
	Blood glucose abnormal	1				3	1	5
	Drug level decreased	1				4		5
	Drug level increased	1				4		5
	Gamma-glutamyltransferase increased				5			5
	Oxygen saturation decreased	3					2	5
	White blood cell count increased					5		5

Cont...

Periodic Report

Number of Adverse Experiences by Body System, Seriousness, Labeling and Geographic
Combined Initial/Follow-up Cases

Body System	Adverse Experience	Number of reports						
		Serious Unlabeled		Serious Labeled		Non Serious		Total
		Domestic	Foreign	Domestic	Foreign	Domestic	Foreign	
	Blood urea increased		1			2	1	4
	Bone density decreased	1				2	1	4
	Drug level					4		4
	Drug screen false positive					4		4
	Haematocrit decreased	1				3		4
	Laboratory test abnormal					4		4
	Liver function test abnormal		2	2				4
	Aspartate aminotransferase increased		1		1	1		3
	Blood glucose decreased			2		1		3
	Blood thyroid stimulating hormone increased					3		3
	Blood urine present			2		1		3
	Body temperature increased	1				1	1	3
	Drug level fluctuating	1				2		3
	Electroencephalogram abnormal	1				2		3
	Glycosylated haemoglobin increased					3		3
	Haemoglobin decreased	1				2		3
	International normalised ratio increased	1	2					3
	Urine analysis abnormal					3		3
	White blood cell count decreased			1		2		3
	Blood cholesterol	1				1		2
	Blood glucose fluctuation			1		1		2
	Blood oestrogen decreased					2		2
	Blood potassium decreased	1	1					2
	Blood potassium increased					2		2
	Blood pressure abnormal					2		2
	Blood testosterone decreased	1				1		2
	Cardiac murmur			2				2
	Creatinine renal clearance decreased	1				1		2
	International normalised ratio decreased		1			1		2
	Intraocular pressure increased					2		2
	Investigation abnormal					2		2
	Low density lipoprotein increased					1	1	2
	Nuclear magnetic resonance imaging abnormal					2		2
	Platelet count decreased			1		1		2
	Prostate examination abnormal	1				1		2
	Protein total increased					2		2
	Protein urine present					2		2
	Red blood cell count decreased					2		2
	Red blood cell sedimentation rate increased					2		2
	Thyroid function test abnormal					2		2
	Vitamin D decreased					2		2
	Ammonia increased					1		1
	Amphetamines positive					1		1
	Antibody test positive	1						1
	Anticoagulation drug level above therapeutic					1		1
	Anticonvulsant drug level abnormal					1		1
	Anticonvulsant drug level decreased					1		1
	Bacterial test positive					1		1
	Bilirubin conjugated increased					1		1
	Blood amylase increased	1						1
	Blood bilirubin increased					1		1
	Blood cortisol decreased					1		1
	Blood count abnormal	1						1
	Blood creatine increased						1	1
	Blood electrolytes abnormal	1						1
	Blood human chorionic gonadotropin abnormal					1		1
	Blood iron decreased	1						1
	Blood magnesium decreased					1		1
	Blood phosphorus increased					1		1
	Blood pressure diastolic decreased			1				1
	Blood pressure immeasurable		1					1

Cont...

Periodic Report

Number of Adverse Experiences by Body System, Seriousness, Labeling and Geographic
Combined Initial/Follow-up Cases

Body System	Adverse Experience	Number of reports						
		Serious Unlabeled		Serious Labeled		Non Serious		Total
		Domestic	Foreign	Domestic	Foreign	Domestic	Foreign	
	Blood pressure orthostatic increased					1		1
	Blood sodium abnormal	1						1
	Blood test abnormal					1		1
	Blood urea abnormal			1				1
	Blood uric acid increased					1		1
	Body height abnormal					1		1
	Body height increased					1		1
	Breath sounds abnormal					1		1
	Cardiac monitoring					1		1
	Cardiac stress test abnormal					1		1
	Catheterisation cardiac	1						1
	Colonoscopy					1		1
	Complement factor increased	1						1
	Computerised tomogram abnormal					1		1
	Creatinine renal clearance increased					1		1
	Drug level above therapeutic					1		1
	Drug level below therapeutic					1		1
	Electrocardiogram QT corrected interval prolonged	1						1
	Electrocardiogram abnormal					1		1
	Electrophoresis abnormal					1		1
	Electrophoresis protein					1		1
	Eosinophil count increased						1	1
	False positive laboratory result					1		1
	Gastric pH decreased					1		1
	General physical condition abnormal					1		1
	Glomerular filtration rate abnormal						1	1
	Glycosylated haemoglobin decreased					1		1
	Grip strength decreased	1						1
	Heart rate abnormal					1		1
	Hepatic enzyme abnormal					1		1
	Hormone level abnormal					1		1
	Investigation					1		1
	Lipase increased	1						1
	Metabolic function test abnormal					1		1
	Nerve conduction studies abnormal					1		1
	Neurological examination abnormal					1		1
	Opiates positive					1		1
	Oxygen saturation					1		1
	Platelet count increased					1		1
	Protein urine					1		1
	Prothrombin time prolonged					1		1
	Pulse abnormal	1						1
	Respiratory rate decreased		1					1
	Respiratory rate increased					1		1
	Transaminases increased						1	1
	Tri-iodothyronine increased					1		1
	Urine output decreased		1					1
	Urine output increased					1		1
	Vitamin B12 decreased						1	1
	White blood cells urine					1		1
	pH body fluid abnormal					1		1
	Sub Totals	39	19	62	20	489	21	650
Metabolism and nutrition disorders								
	Diabetes mellitus	2	3	5		10		20
	Anorexia			2		15	2	19
	Fluid retention	1				17		18
	Dehydration	2	1	5	1	3		12
	Increased appetite					10		10
	Decreased appetite					8	1	9
	Hypoglycaemia			2		2		4
	Hypokalaemia	4						4
	Oral intake reduced	1				3		4
	Glucose tolerance impaired					3		3
	Gout					3		3
	Hyponatraemia				2	1		3
	Malnutrition	1				2		3
	Diabetes mellitus non-insulin-dependent			1		1		2

Cont...

Periodic Report

Number of Adverse Experiences by Body System, Seriousness, Labeling and Geographic
Combined Initial/Follow-up Cases

Body System	Adverse Experience	Number of reports						
		Serious Unlabeled		Serious Labeled		Non Serious		Total
		Domestic	Foreign	Domestic	Foreign	Domestic	Foreign	
	Electrolyte imbalance	1				1		2
	Hyperammonaemia	1	1					2
	Hyperglycaemia					2		2
	Hyperlipidaemia					2		2
	Hyperphagia					2		2
	Polydipsia					2		2
	Vitamin D deficiency					2		2
	Weight fluctuation					2		2
	Weight loss poor					2		2
	Diabetes mellitus inadequate control					1		1
	Diabetes mellitus insulin-dependent			1				1
	Diabetic foot		1					1
	Electrolyte depletion					1		1
	Fluid overload			1				1
	Food craving					1		1
	Gestational diabetes	1						1
	Hypercholesterolaemia					1		1
	Hypernatraemia	1						1
	Hypoalbuminaemia		1					1
	Hypomagnesaemia	1						1
	Hypovolaemia	1						1
	Metabolic acidosis	1						1
	Metabolic disorder					1		1
	Obesity					1		1
	Overweight					1		1
	Underweight					1		1
	Sub Totals	18	7	17	3	109	3	157
Musculoskeletal and connective tissue disorders								
	Pain in extremity	2		2	1	62	3	70
	Back pain			3		51	1	55
	Muscle spasms	1	2			45	3	51
	Arthralgia			5	5	29		39
	Arthritis	2		4		31		37
	Myalgia				2	31		33
	Muscular weakness	1	2	4	2	12	2	23
	Fibromyalgia	3				19		22
	Arthropathy	5				8		13
	Osteoporosis			1		12		13
	Back disorder	4				7		11
	Intervertebral disc protrusion	8	1			2		11
	Joint swelling		1			10		11
	Limb discomfort					11		11
	Musculoskeletal stiffness	1				10		11
	Osteoarthritis	1	1			9		11
	Muscle tightness					10		10
	Muscle twitching					9		9
	Neck pain			2		7		9
	Spinal column stenosis	6				2		8
	Intervertebral disc disorder	5				2		7
	Sensation of heaviness		1			6		7
	Spinal disorder	2				5		7
	Exostosis	3				3		6
	Joint stiffness				1	5		6
	Musculoskeletal discomfort	1				5		6
	Rhabdomyolysis	5	1					6
	Shoulder pain	1		1		4		6
	Bone pain	1				4		5
	Intervertebral disc degeneration	2				3		5
	Mobility decreased	2	1			2		5
	Muscle atrophy	2				3		5
	Systemic lupus erythematosus	4				1		5
	Toe deformity	2				3		5
	Bone disorder	2	1			1		4
	Muscle disorder					4		4
	Spinal osteoarthritis	2				2		4
	Bursitis			1		2		3
	Foot deformity					3		3
	Groin pain					3		3
	Musculoskeletal chest pain					3		3
	Polymyalgia rheumatica					3		3
	Rheumatoid arthritis			1		2		3
	Rotator cuff syndrome	3						3
	Temporomandibular joint syndrome	1				2		3

Cont...

Periodic Report

Number of Adverse Experiences by Body System, Seriousness, Labeling and Geographic
Combined Initial/Follow-up Cases

Body System	Adverse Experience	Number of reports						
		Serious Unlabeled		Serious Labeled		Non Serious		Total
		Domestic	Foreign	Domestic	Foreign	Domestic	Foreign	
	Bunion	1				1		2
	Chondropathy	2						2
	Head deformity	2						2
	Lumbar spinal stenosis	1				1		2
	Muscle rigidity		2					2
	Osteopenia					2		2
	Pain in jaw					2		2
	Scoliosis	1				1		2
	Sjogren's syndrome	1				1		2
	Tendonitis					2		2
	Trismus					2		2
	Ankylosing spondylitis		1					1
	Bone development abnormal	1						1
	Buttock pain					1		1
	Cataplexy		1					1
	Cervical spinal stenosis	1						1
	Compartment syndrome					1		1
	Connective tissue disorder	1						1
	Joint contracture					1		1
	Joint crepitation					1		1
	Joint lock					1		1
	Kyphosis					1		1
	Myopathy		1					1
	Nuchal rigidity					1		1
	Osteomalacia	1						1
	Osteonecrosis	1						1
	Periarthritis					1		1
	Plantar fasciitis					1		1
	Polyarthritis					1		1
	Posture abnormal	1						1
	Tenosynovitis					1		1
	Sub Totals	86	16	24	11	471	9	617
Neoplasms benign, malignant and unspecified (incl cysts and polyps)								
	Breast cancer	4		5				9
	Lung neoplasm malignant	5	1					6
	Neoplasm malignant	4	1					5
	Breast cancer recurrent	2						2
	Lymphoma	2						2
	Myelodysplastic syndrome		2					2
	Neoplasm skin		1			1		2
	Squamous cell carcinoma	2						2
	Thyroid neoplasm	2						2
	Adenoma benign					1		1
	Benign neoplasm	1						1
	Bone neoplasm malignant	1						1
	Carcinoid tumour	1						1
	Chronic lymphocytic leukaemia recurrent		1					1
	Gammopathy	1						1
	Lipoma	1						1
	Lymphoproliferative disorder	1						1
	Metastases to lymph nodes	1						1
	Metastases to spine	1						1
	Metastasis		1					1
	Metastatic carcinoma of the bladder	1						1
	Metastatic neoplasm		1					1
	Multiple myeloma	1						1
	Neoplasm	1						1
	Neoplasm progression		1					1
	Neuroma	1						1
	Non-Hodgkin's lymphoma			1				1
	Non-Hodgkin's lymphoma recurrent	1						1
	Oesophageal carcinoma	1						1
	Ovarian cancer	1						1
	Peritoneal carcinoma	1						1
	Renal cell carcinoma stage unspecified	1						1
	Spinal cord neoplasm	1						1
	T-cell lymphoma	1						1
	Thyroid gland cancer	1						1
	Tumour lysis syndrome	1						1
	Waldenstrom's macroglobulinaemia	1						1
	Sub Totals	43	9	6		2		60

Periodic Report

Number of Adverse Experiences by Body System, Seriousness, Labeling and Geographic
Combined Initial/Follow-up Cases

Body System	Adverse Experience	Number of reports						
		Serious Unlabeled		Serious Labeled		Non Serious		Total
		Domestic	Foreign	Domestic	Foreign	Domestic	Foreign	
Nervous system disorders								
	Somnolence	3		7	7	194	10	221
	Dizziness			6	8	174	8	196
	Headache			4	2	101	5	112
	Convulsion	20	3	58	7	4	1	93
	Tremor	2	1	4	7	69	3	86
	Neuropathy	2	1	1		70		74
	Hypoaesthesia	2		3	1	62	2	70
	Paraesthesia			3	1	60	1	65
	Amnesia	1		10	4	46	1	62
	Neuralgia	3	1			55	1	60
	Balance disorder	6		1		47	2	56
	Memory impairment	1	2	1		43	2	49
	Burning sensation	1				46	1	48
	Disturbance in attention	1				37		38
	Cerebrovascular accident	2	3	29	2			36
	Speech disorder	2	1	2	3	24	1	33
	Loss of consciousness	11	9	6		3		29
	Neuropathy peripheral	6		4		18		28
	Coordination abnormal			3	3	21		27
	Sedation		3			22	1	26
	Dyskinesia	1		2	2	20		25
	Mental impairment	3	1			19	1	24
	Coma	12	10		1			23
	Lethargy	3				20		23
	Migraine	1		1		18		20
	Dysarthria	1		1	1	15	1	19
	Movement disorder	6		3		10		19
	Dysstasia	9	1			6		16
	Complex regional pain syndrome	4				11		15
	Transient ischaemic attack	2		12				14
	Cognitive disorder	4	1			7		12
	Diabetic neuropathy	2		1		9		12
	Epilepsy	3	7		2			12
	Syncope			5	4	3		12
	Aphasia	2		3	2	4		11
	Restless legs syndrome					11		11
	Dysgeusia		1			9		10
	Nervous system disorder	5	1			4		10
	Paralysis	7	2			1		10
	Facial palsy	3		2		4		9
	Hypersomnia					9		9
	Myoclonus	1		1	5	2		9
	Psychomotor hyperactivity					9		9
	Trigeminal neuralgia	2				7		9
	Clumsiness					8		8
	Depressed level of consciousness	3	3			1	1	8
	Encephalopathy	2		2	4			8
	Post herpetic neuralgia	1				7		8
	Sensory disturbance	1	1			5	1	8
	Carpal tunnel syndrome	4				3		7
	Grand mal convulsion	5	1		1			7
	Multiple sclerosis	4	1			2		7
	Cerebral haemorrhage	3	3					6
	Hyperaesthesia					6		6
	Incoherent	2			1	3		6
	Nerve compression	2				4		6
	Poor quality sleep			1		5		6
	Dementia Alzheimer's type	2	1			2		5
	Head discomfort				1	4		5
	Hemiplegia		1	3	1			5
	Radiculopathy	1				4		5
	Ageusia			1		3		4
	Demyelination	2				2		4
	Formication					4		4
	Motor dysfunction					4		4
	Parkinson's disease	2				2		4
	Parosmia		1			3		4
	Partial seizures	3		1				4
	Stupor			1	1	2		4
	Anosmia	1				2		3
	Brain damage	3						3
	Dysgraphia		1			2		3
	Hemiparesis		1			2		3
	Hypokinesia					3		3
	Hypotonia		1	1		1		3

Cont...

Periodic Report

Number of Adverse Experiences by Body System, Seriousness, Labeling and Geographic
Combined Initial/Follow-up Cases

Body System	Adverse Experience	Number of reports						
		Serious Unlabeled		Serious Labeled		Non Serious		Total
		Domestic	Foreign	Domestic	Foreign	Domestic	Foreign	
	Parkinsonism		1			2		3
	Peroneal nerve palsy	1				2		3
	Sciatica					3		3
	Sensory loss	1	2					3
	Simple partial seizures	1	2					3
	Subarachnoid haemorrhage	3						3
	Aphonia					2		2
	Arachnoid cyst	1				1		2
	Asterixis	2						2
	Aura					2		2
	Carotid artery occlusion	2						2
	Cerebral disorder	1	1					2
	Complex partial seizures	2						2
	Dystonia			1		1		2
	Encephalomalacia	2						2
	Facial nerve disorder					2		2
	Haemorrhagic stroke			2				2
	Muscle spasticity					2		2
	Neuroleptic malignant syndrome		2					2
	Status epilepticus	2						2
	Tarsal tunnel syndrome	2						2
	Allodynia					1		1
	Anoxic encephalopathy	1						1
	Anticholinergic syndrome					1		1
	Apallic syndrome	1						1
	Apraxia					1		1
	Arachnoiditis	1						1
	Autism					1		1
	Benign intracranial hypertension	1						1
	Brain oedema	1						1
	Carotid artery stenosis		1					1
	Central nervous system lesion	1						1
	Cerebellar syndrome					1		1
	Cerebral ischaemia		1					1
	Cervicobrachial syndrome	1						1
	Chorea					1		1
	Clonus			1				1
	Cranial nerve disorder	1						1
	Dementia					1		1
	Diabetic coma	1						1
	Diplegia	1						1
	Dizziness postural					1		1
	Drop attacks	1						1
	Dysphasia		1					1
	Epileptic aura					1		1
	Glossopharyngeal neuralgia					1		1
	Guillain-Barre syndrome		1					1
	Head titubation					1		1
	Hypertonia					1		1
	Hyporeflexia					1		1
	Hyposmia					1		1
	Intracranial haematoma	1						1
	Lacunar infarction	1						1
	Lhermitte's sign					1		1
	Lumbar radiculopathy	1						1
	Masked facies					1		1
	Monoparesis				1			1
	Monoplegia	1						1
	Mutism		1					1
	Myasthenia gravis	1						1
	Narcolepsy		1					1
	Nerve root compression					1		1
	Nerve root lesion		1					1
	Neuritis			1				1
	Optic neuritis		1					1
	Paraparesis			1				1
	Paraplegia	1						1
	Paresis				1			1
	Peripheral motor neuropathy	1						1
	Peripheral sensory neuropathy	1						1
	Petit mal epilepsy	1						1
	Phantom pain					1		1
	Pneumocephalus	1						1
	Polyneuropathy					1		1
	Sinus headache					1		1
	Sleep talking					1		1
	Speech disorder developmental					1		1
	Spinal cord disorder	1						1

Cont...

Periodic Report

Number of Adverse Experiences by Body System, Seriousness, Labeling and Geographic
Combined Initial/Follow-up Cases

Body System	Adverse Experience	Number of reports						
		Serious Unlabeled		Serious Labeled		Non Serious		Total
		Domestic	Foreign	Domestic	Foreign	Domestic	Foreign	
	Temporal lobe epilepsy	1						1
	Tension headache					1		1
	Tongue biting					1		1
	Unresponsive to pain stimuli	1						1
	Vagus nerve disorder					1		1
	Vascular dementia		1					1
	Vascular encephalopathy		1					1
	Visual field defect			1				1
	Sub Totals	219	81	190	73	1420	43	2026
Pregnancy, puerperium and perinatal conditions								
	Abortion spontaneous		4					4
	Unintended pregnancy		1				1	2
	Antepartum haemorrhage		1					1
	Premature separation of placenta		1					1
	Uterine contractions abnormal		1					1
	Sub Totals		8				1	9
Psychiatric disorders								
	Suicide attempt	4		278	1			283
	Suicidal ideation	4	1	188	2	6	1	202
	Depression	11		21	2	100		134
	Insomnia				1	89	1	91
	Completed suicide	51	1	38				90
	Anxiety	8	1	5		64	2	80
	Confusional state			4	9	43	2	58
	Sleep disorder	1	2			39	2	44
	Agitation			3	2	22	2	29
	Abnormal behaviour	4	1	1		21		27
	Nervousness					26		26
	Mental disorder	9	1			14		24
	Mood swings					19	1	20
	Stress	1				19		20
	Euphoric mood				1	16	2	19
	Hallucination	1		6	1	11		19
	Thinking abnormal	1	1	1		16		19
	Drug dependence	10	4			4		18
	Psychotic disorder	2	1	10	1	3		17
	Disorientation	2	1	1	1	11		16
	Aggression	3	3	2		6	1	15
	Anger	3				11		14
	Panic attack		1			13		14
	Bipolar disorder	7	1			5		13
	Crying					12		12
	Hallucination, auditory	3	2	2	1	3		11
	Paranoia			5	2	4		11
	Restlessness			1	1	9		11
	Abnormal dreams			1		9		10
	Affect lability					10		10
	Mood altered		1			8	1	10
	Personality change	1	1			8		10
	Hallucination, visual	1	1	1	2	4		9
	Fear					8		8
	Major depression	2		6				8
	Nightmare					8		8
	Affective disorder	1				4	2	7
	Depressed mood				1	6		7
	Emotional disorder			1		6		7
	Mental status changes	4		1		2		7
	Emotional distress			1		5		6
	Homicidal ideation	5		1				6
	Personality disorder	2				4		6
	Decreased activity		1			4		5
	Dissociation					5		5
	Hostility			2		3		5
	Intentional self-injury	4		1				5
	Logorrhoea					5		5
	Mania			1		4		5
	Tension					5		5
	Anorgasmia					4		4
	Bradyphrenia	1				3		4
	Dependence	3	1					4
	Eating disorder					4		4
	Initial insomnia					4		4
	Obsessive-compulsive disorder	1				3		4
	Alcoholism	2				1		3

Periodic Report

Number of Adverse Experiences by Body System, Seriousness, Labeling and Geographic
Combined Initial/Follow-up Cases

Body System	Adverse Experience	Number of reports						
		Serious Unlabeled		Serious Labeled		Non Serious		Total
		Domestic	Foreign	Domestic	Foreign	Domestic	Foreign	
								Cont . . .
	Apathy			1		2		3
	Bipolar I disorder	2				1		3
	Delusion	2	1					3
	Dysphemia					3		3
	Loss of libido					3		3
	Panic disorder	1				2		3
	Panic reaction					3		3
	Reading disorder					3		3
	Communication disorder	1				1		2
	Feeling of despair					1	1	2
	Generalised anxiety disorder					2		2
	Hypomania			1	1			2
	Impulse-control disorder	2						2
	Impulsive behaviour					2		2
	Inappropriate affect	1				1		2
	Lack of spontaneous speech			1		1		2
	Laziness					2		2
	Middle insomnia					2		2
	Neurosis					2		2
	Post-traumatic stress disorder	1				1		2
	Psychogenic pain disorder					2		2
	Schizoaffective disorder	2						2
	Screaming					2		2
	Self injurious behaviour	2						2
	Self-injurious ideation			1			1	2
	Somatoform disorder					2		2
	Stereotypy		2					2
	Suicidal behaviour			2				2
	Adjustment disorder					1		1
	Adjustment disorder with anxiety					1		1
	Adjustment disorder with disturbance of conduct	1						1
	Alcohol problem					1		1
	Alcoholic hangover					1		1
	Anxiety disorder			1				1
	Bereavement reaction					1		1
	Bipolar II disorder	1						1
	Bruxism	1						1
	Catatonia		1					1
	Conversion disorder	1						1
	Delirium	1						1
	Delirium tremens	1						1
	Delusional perception					1		1
	Derealisation					1		1
	Disinhibition					1		1
	Distractibility					1		1
	Dysphoria					1		1
	Early morning awakening					1		1
	Elevated mood					1		1
	Excitability					1		1
	Expressive language disorder						1	1
	Feelings of worthlessness					1		1
	Flat affect					1		1
	Hallucination, tactile					1		1
	Ideas of reference		1					1
	Illogical thinking					1		1
	Illusion		1					1
	Impaired self-care	1						1
	Impatience					1		1
	Libido decreased					1		1
	Listless					1		1
	Loss of dreaming					1		1
	Moaning					1		1
	Negative thoughts	1						1
	Neglect of personal appearance					1		1
	Phobia of driving					1		1
	Psychosomatic disease					1		1
	Schizophrenia	1						1
	Schizophrenia, paranoid type	1						1
	Schizophreniform disorder	1						1
	School refusal					1		1
	Self esteem decreased					1		1
	Sleep terror		1					1
	Somatisation disorder					1		1
	Tearfulness					1		1
	Trance					1		1

Cont...

Periodic Report

Number of Adverse Experiences by Body System, Seriousness, Labeling and Geographic
Combined Initial/Follow-up Cases

Body System	Adverse Experience	Number of reports						
		Serious Unlabeled		Serious Labeled		Non Serious		Total
		Domestic	Foreign	Domestic	Foreign	Domestic	Foreign	
	Sub Totals	177	33	589	29	781	20	1629
Renal and urinary disorders								
	Renal failure	3		7	3	1		14
	Pollakiuria					12		12
	Urinary incontinence				1	11		12
	Dysuria			3	1	5		9
	Renal disorder	4		1		3		8
	Bladder disorder	3				2		5
	Incontinence					5		5
	Urinary retention	1				4		5
	Enuresis					3		3
	Nephrolithiasis			1		2		3
	Renal failure acute			2	1			3
	Chromaturia					2		2
	Hypertonic bladder					2		2
	Micturition disorder					2		2
	Micturition urgency					2		2
	Polyuria					1	1	2
	Pyuria					2		2
	Renal failure chronic		2					2
	Renal impairment			1	1			2
	Renal pain					1	1	2
	Urine odour abnormal					2		2
	Bladder hypertrophy	1						1
	Bladder pain					1		1
	Bladder prolapse	1						1
	Bladder spasm					1		1
	Cystitis interstitial		1					1
	Haematuria					1		1
	Neurogenic bladder		1					1
	Renal artery occlusion	1						1
	Renal cyst					1		1
	Renal tubular necrosis	1						1
	Tubulointerstitial nephritis		1					1
	Urinary tract disorder		1					1
	Sub Totals	15	6	15	7	66	2	111
Reproductive system and breast disorders								
	Erectile dysfunction					18		18
	Breast tenderness					4		4
	Ejaculation failure					3		3
	Vulvovaginal discomfort					3		3
	Breast mass	2						2
	Breast pain					2		2
	Epididymitis			2				2
	Menorrhagia					2		2
	Oligomenorrhoea					2		2
	Polymenorrhoea	1				1		2
	Sexual dysfunction					2		2
	Vaginal haemorrhage					2		2
	Amenorrhoea					1		1
	Breast discharge					1		1
	Breast swelling					1		1
	Dysmenorrhoea					1		1
	Ejaculation disorder					1		1
	Erection increased					1		1
	Galactorrhoea					1		1
	Genital pain male					1		1
	Gynaecomastia					1		1
	Male sexual dysfunction					1		1
	Menstrual disorder					1		1
	Menstruation irregular					1		1
	Nipple disorder						1	1
	Ovarian cyst	1						1
	Ovarian enlargement					1		1
	Pelvic floor muscle weakness	1						1
	Pelvic pain					1		1
	Premenstrual syndrome	1						1
	Priapism	1						1
	Prostatic disorder	1						1
	Vaginal burning sensation					1		1
	Vaginal pain					1		1
	Sub Totals	8		2		55	1	66
Respiratory, thoracic and mediastinal disorders								

Cont...

Periodic Report

Number of Adverse Experiences by Body System, Seriousness, Labeling and Geographic
Combined Initial/Follow-up Cases

Body System	Adverse Experience	Number of reports						
		Serious Unlabeled		Serious Labeled		Non Serious		Total
		Domestic	Foreign	Domestic	Foreign	Domestic	Foreign	
	Dyspnoea	1		25	4	26	2	58
	Asthma	3	2	3		8		16
	Respiratory failure	11	3					14
	Respiratory arrest	9	3					12
	Cough			1		9	1	11
	Throat tightness	7				3		10
	Chronic obstructive pulmonary disease	6	1			2		9
	Epistaxis			2		7		9
	Pharyngolaryngeal pain		1			8		9
	Dysphonia	1		1		3	1	6
	Emphysema	4				2		6
	Lung disorder	3		1		2		6
	Pharyngeal oedema	2	3			1		6
	Pulmonary oedema	1	1	3	1			6
	Sinus disorder					6		6
	Sleep apnoea syndrome	1				5		6
	Pneumonia aspiration	2		3				5
	Pulmonary congestion	3				1		4
	Atelectasis	2				1		3
	Pulmonary embolism	1		1	1			3
	Pulmonary fibrosis		3					3
	Pulmonary hypertension	2	1					3
	Respiratory depression	1	2					3
	Throat irritation					3		3
	Wheezing		1	1			1	3
	Apnoea			1		1		2
	Asphyxia	1	1					2
	Aspiration	2						2
	Choking	1				1		2
	Dry throat					2		2
	Haemopneumothorax	2						2
	Haemoptysis			2				2
	Hyperventilation					2		2
	Increased upper airway secretion					2		2
	Nasal congestion					2		2
	Pleural effusion	1				1		2
	Rhinorrhoea					2		2
	Acute pulmonary oedema			1				1
	Acute respiratory distress syndrome	1						1
	Bradypnoea		1					1
	Bronchial hyperactivity	1						1
	Bronchospasm				1			1
	Cheyne-Stokes respiration		1					1
	Cyanosis neonatal		1					1
	Dyspnoea exertional					1		1
	Foreign body aspiration	1						1
	Hypercapnia		1					1
	Hypoventilation			1				1
	Hypoxia		1					1
	Interstitial lung disease	1						1
	Nasal disorder	1						1
	Nasal dryness					1		1
	Nasal polyps					1		1
	Pharyngeal hypoaesthesia					1		1
	Pickwickian syndrome		1					1
	Pleural fibrosis					1		1
	Pleurisy					1		1
	Pleuritic pain					1		1
	Pneumomediastinum	1						1
	Pneumonitis		1					1
	Pulmonary granuloma					1		1
	Pulmonary mass	1						1
	Pulmonary thrombosis			1				1
	Respiratory distress	1						1
	Sinus congestion					1		1
	Sneezing					1		1
	Suffocation feeling					1		1
	Vocal cord polyp	1						1
	Sub Totals	76	29	47	7	111	5	275
Skin and subcutaneous tissue disorders								
	Rash	1		2	4	40	1	48
	Pruritus			1	2	37	3	43
	Alopecia					33		33
	Hyperhidrosis				2	28		30
	Urticaria			1	1	19		21

Cont...

Periodic Report

Number of Adverse Experiences by Body System, Seriousness, Labeling and Geographic
Combined Initial/Follow-up Cases

Body System	Adverse Experience	Number of reports						
		Serious Unlabeled		Serious Labeled		Non Serious		Total
		Domestic	Foreign	Domestic	Foreign	Domestic	Foreign	
	Erythema		1			13		14
	Swelling face		3	2		6		11
	Blister	1				5		6
	Skin discolouration					5	1	6
	Skin disorder		1			5		6
	Photosensitivity reaction	1				3	1	5
	Rash macular		1			4		5
	Scar	1				4		5
	Skin lesion					4	1	5
	Cold sweat					4		4
	Ecchymosis	1				2	1	4
	Rash maculo-papular		1	1	1	1		4
	Rash pruritic					4		4
	Skin ulcer		1	1		2		4
	Acne					3		3
	Angioneurotic oedema			3				3
	Dry skin					3		3
	Skin burning sensation					3		3
	Cutaneous vasculitis		2					2
	Dermatitis bullous				1		1	2
	Dermatitis exfoliative		2					2
	Eczema		1	1				2
	Lichen planus	1				1		2
	Neurodermatitis					2		2
	Night sweats					2		2
	Pain of skin					2		2
	Psoriasis		1	1				2
	Purpura				2			2
	Rash generalised						2	2
	Rosacea					2		2
	Skin exfoliation					2		2
	Actinic keratosis					1		1
	Acute febrile neutrophilic dermatosis					1		1
	Blood blister					1		1
	Dandruff					1		1
	Decubitus ulcer					1		1
	Dermatitis					1		1
	Hypoaesthesia facial					1		1
	Hypotrichosis					1		1
	Increased tendency to bruise						1	1
	Ingrowing nail	1						1
	Leukocytoclastic vasculitis	1						1
	Male pattern baldness					1		1
	Nail discolouration					1		1
	Nail growth abnormal					1		1
	Palmar erythema					1		1
	Petechiae		1					1
	Precancerous skin lesion					1		1
	Pruritus generalised					1		1
	Rash erythematous					1		1
	Scab					1		1
	Seborrhoeic dermatitis					1		1
	Skin atrophy					1		1
	Skin chapped					1		1
	Skin depigmentation					1		1
	Skin discomfort					1		1
	Skin erosion					1		1
	Skin inflammation					1		1
	Skin irritation					1		1
	Skin reaction	1						1
	Skin striae					1		1
	Stevens-Johnson syndrome			1				1
	Trichorrhexis					1		1
	Yellow skin					1		1
	Sub Totals	9	15	14	13	266	12	329
Social circumstances								
	Disability	17				4		21
	Activities of daily living impaired	6	2			9		17
	Impaired driving ability		1			12		13
	Impaired work ability	6	1			4	1	12
	Drug abuser	7	2			2		11
	Bedridden	5	2			2		9
	Wheelchair user	5						5
	Menopause					3		3
	Physical disability	2	1					3
	Polysubstance abuse	3						3

Cont...

Periodic Report

Number of Adverse Experiences by Body System, Seriousness, Labeling and Geographic
Combined Initial/Follow-up Cases

Body System	Adverse Experience	Number of reports						
		Serious Unlabeled		Serious Labeled		Non Serious		Total
		Domestic	Foreign	Domestic	Foreign	Domestic	Foreign	
	Corrective lens user					2		2
	Job dissatisfaction	1				1		2
	Victim of crime	1				1		2
	Walking aid user	2						2
	Walking disability	1	1					2
	Economic problem					1		1
	Imprisonment	1						1
	Learning disability					1		1
	Parent-child problem	1						1
	Partner stress	1						1
	Physical abuse					1		1
	Physical assault					1		1
	Social problem					1		1
	Truancy					1		1
	Victim of abuse					1		1
	Sub Totals	59	10			47	1	117
Surgical and medical procedures								
	Surgery	25	3					28
	Knee arthroplasty	8						8
	Spinal laminectomy	5	1					6
	Hysterectomy	5						5
	Spinal fusion surgery	5						5
	Spinal operation	4	1					5
	Face lift	4						4
	Knee operation	4						4
	Stent placement	4						4
	Cardiac operation	3						3
	Coronary arterial stent insertion	3						3
	Dialysis	3						3
	Hip arthroplasty	3						3
	Therapy regimen changed					3		3
	Amputation	2						2
	Brain operation	1	1					2
	Cardiac pacemaker insertion	1	1					2
	Eye operation	2						2
	Gastric bypass	2						2
	Haemodialysis		2					2
	Nerve block	1				1		2
	Peripheral nerve operation	2						2
	Shoulder operation	2						2
	Toe operation	2						2
	Tracheostomy	2						2
	Triple vessel bypass graft	2						2
	Analgesic intervention supportive therapy					1		1
	Appendicectomy	1						1
	Bladder operation	1						1
	Bunion operation	1						1
	Carpal tunnel decompression	1						1
	Cataract operation	1						1
	Colon operation	1						1
	Cryotherapy	1						1
	Cyst drainage	1						1
	Cyst removal	1						1
	Dental implantation	1						1
	Drug therapy					1		1
	Drug therapy changed					1		1
	Eye excision	1						1
	Eye laser surgery	1						1
	Foot operation		1					1
	Forceps delivery		1					1
	Gallbladder operation	1						1
	Gamma radiation therapy	1						1
	Heart valve replacement	1						1
	Hip surgery	1						1
	Hospitalisation	1						1
	Implantable defibrillator replacement	1						1
	Intervertebral disc operation	1						1
	Intestinal operation	1						1
	Joint stabilisation					1		1
	Leg amputation	1						1
	Life support	1						1
	Nervous system surgery		1					1
	Prostatic operation	1						1
	Resuscitation	1						1
	Sinus operation	1						1

Cont...

Periodic Report

Number of Adverse Experiences by Body System, Seriousness, Labeling and Geographic
Combined Initial/Follow-up Cases

Body System	Adverse Experience	Number of reports						
		Serious Unlabeled		Serious Labeled		Non Serious		Total
		Domestic	Foreign	Domestic	Foreign	Domestic	Foreign	
	Spinal cord operation	1						1
	Spinal nerve stimulator implantation	1						1
	Splenectomy	1						1
	Tendon operation	1						1
	Tendon transfer	1						1
	Toe amputation	1						1
	Ureteric diversion operation	1						1
	Uterine operation	1						1
	Vena cava filter insertion	1						1
	Venous operation	1						1
	Vestibular apparatus operation	1						1
	Sub Totals	131	12			8		151
Vascular disorders								
	Hypertension	1	1	4		43		49
	Hypotension	2		8	1	5	4	20
	Haemorrhage	8	1			1		10
	Hot flush					9		9
	Flushing					8		8
	Pallor		1			4	1	6
	Deep vein thrombosis	1	1	1	2			5
	Blood pressure fluctuation	2				1	1	4
	Thrombosis	2	1	1				4
	Circulatory collapse	3						3
	Lymphoedema	1				2		3
	Angiopathy	1					1	2
	Aortic aneurysm	1	1					2
	Arterial occlusive disease	1				1		2
	Orthostatic hypotension		2					2
	Poor peripheral circulation	1				1		2
	Shock		2					2
	Aneurysm	1						1
	Aortic arteriosclerosis					1		1
	Arterial disorder					1		1
	Arterial thrombosis	1						1
	Blood pressure inadequately controlled					1		1
	Embolism	1						1
	Hyperaemia					1		1
	Infarction		1					1
	Ischaemia	1						1
	Jugular vein thrombosis	1						1
	Lymphangiectasia	1						1
	Peripheral artery aneurysm					1		1
	Peripheral ischaemia		1					1
	Peripheral vascular disorder					1		1
	Temporal arteritis			1				1
	Vasculitis		1					1
	Vasoconstriction					1		1
	Vasodilatation				1			1
	Venous occlusion					1		1
	Sub Totals	30	13	15	4	83	7	152
	Grand Totals	1502	421	1271	250	7330	245	11019

PERIODIC REPORT

NARRATIVE SUMMARY OF ACTIONS TAKEN

A: Listing of Labeling Changes Made During the Reporting Period

The package insert corresponding to Neurontin Capsules (NDA# 20-235), Neurontin Tablets (NDA# 20-882), and Neurontin Oral Solution (NDA# 21-129) underwent multiple revisions from LAB-0106-6 (May 2004). These included LAB-0106-7.0 (April 2005) and LAB-0106-8.0 (December 2005). The package insert (Greenstone) corresponding to Gabapentin Capsules (NDA# 20-235), Gabapentin Tablets (NDA# 20-882), and Gabapentin Oral Solution (NDA# 21-129) underwent multiple revisions from LAB-0290-2 (September 2004). These included LAB-0290-3.0 (April 2005) and LAB-0290-4.0 (December 2005).

The following same changes were made in the package inserts:

In the **ADVERSE REACTIONS** section, **Other Adverse Events Observed During All Clinical Trials** subsection, under Clinical Trials in Adults and Adolescents (Except Clinical Trials in Neuropathic Pain), the following changes were made:

The number of patients was changed from 2074 to 4717.

In the Nervous System paragraph, the events of "suicidal" and "suicidal gesture" were deleted, and replaced with the events of "suicide attempt" and "suicide".

In the **ADVERSE REACTIONS** section, **Clinical Trials in Adults with Neuropathic Pain of Various Etiologies** subsection, in the Nervous System paragraph, **the event of "suicide attempt" was added.**

In the **ADVERSE REACTIONS** section, **Postmarketing and Other Experience** subsection, the following change was made:

The words "such as dyskinesia" were removed from the first paragraph, and the paragraph reads as: "In addition to the adverse experiences reported during clinical testing of Neurontin, the following adverse experiences have been reported in patients receiving marketed Neurontin. These adverse experiences have not been listed above and data are insufficient to support an estimate of their incidence or to establish causation. The listing is alphabetized: angioedema, blood glucose fluctuation, erythema multiforme, elevated liver function tests, fever, hyponatremia, jaundice, movement disorder, Stevens-Johnson syndrome."

In the **DOSAGE AND ADMINISTRATION** section, the second paragraph was updated to: "If Neurontin dose is reduced, discontinued or substituted with an alternative medication, this should be done gradually over a minimum of 1 week (a longer period may be needed at the discretion of the prescriber)."

The labeling revisions also consisted of minor editorial and cosmetic changes that were not a result of any adverse or safety-related events.

These changes are highlighted on the attached package inserts.

B: Current Labeling- Copies of the current labeling for the above mentioned NDA #'s are attached.